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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,343	12/28/2001	Dennis McDevitt	9417.17584-CIP	8332

7590            06/18/2003

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[REDACTED] EXAMINER

ROBERT, EDUARDO C

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/034,343	MCDEVITT ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Eduardo C. Robert	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final..
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-14 is/are pending in the application.
  - 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 and 10-12 is/are rejected.
- 7) Claim(s) 8 and 9 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 December 2001 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>6</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____   |

**DETAILED ACTION**

Claim 13 has been treated as an independent claim because it is directed to a different device, i.e. an insertion tool, than that of claim 1, i.e. an implant, and it does not pass the infringement test (see MPEP 608.01(n)(III) ), i.e. claim 13 can be infringed without infringing claim 1 since claim 1 is only functionally recited. Thus, claim 13 and dependent claim 14 have been treated as being directed to an insertion tool.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to an implant, classified in class 623, subclass 19.11.
- II. Claims 13 and 14, drawn to insertion tool, classified in class 606, subclass 104.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as a prosthetic implant and invention II has a separate utility such as an inserter for screws of bone plates. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Daniel D. Ryan on June 10, 2003 a provisional election was made **without traverse** to prosecute the invention I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13 and 14 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The Declaration filed on April 16, 2002 states that it is for a continuation-in part (CIP) (see page 1) and that it is claiming benefit of an earlier application under 35 USC 120 using *provisional application 60/332,170* having a filing date of September 11, 2001 (see "Added page

to combined declaration", page 1). It is noted that Applicants can not claim benefit of an earlier application under 35 USC 120 with a provisional application, however, they can do it under 35 USC 119(e) (see MPEP 201.11). Moreover, a continuation-in-part application **must** claim the benefit of a prior **non-provisional application** under 35 USC 120 or 365(c) (see MPEP 201.08). Also, an application claiming the benefit of a provisional application under 35 USC 119(e) should not be called a "continuation-in-part" of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation-in-part of the provisional application (see MPEP 201.08).

Also, Applicants claim that the provisional application 60/332,170 was filed on September 11, 2001. However, this information is not consistent with PTO records, which show a filing date of September 15, 2001.

Applicant is advised to fix the above mention problems and to file a new declaration. *It is noted that for examination purposes the application would considered as claiming benefit under 35 USC 119(e) with provisional application 60/332,170 and the filing date of September 15, 2001.*

### *Specification*

The abstract of the disclosure is objected to because it contains "means" and it is not a concise statement of the technical disclosure of the patent and it does not include that which is new in the art to which the invention pertains . Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 2 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 2, lines 2-3, applicant positively recites part of a human, i.e. "wherein expansion of the stem compresses surrounding bone structure" Thus claim 2 includes a human within its scope and is non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

### *Claim Objections*

Claims 7-9 are objected to because of the following informalities:

In claim 7, line 1, "The" should be changed to -- A --.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 4-6, and 10-12, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Powell (Reference "F" on PTO-1449).

Powell discloses an implant comprising a base 312 including at least one stem 316 which is capable of engaging one void created in a bone structure. The stem 316 has an exterior peripherally surrounding an interior lumen (see Figures 31 and 32). The implant also includes a pin 336 that fits into the interior lumen and expands the exterior of the stem 316 (see page 21, lines 2-4). The implant has a cap, e.g. 320, from which the pin 336 depends, wherein fitting the pin into the interior lumen of the stem couples the cap to the base (see Figures 31 and 32). The cap includes a bearing surface, e.g. tapered post for ball, and the pin depends from the cap from a surface that faces away from the bearing surface (see Figures 31 and 32). The cap and base include nesting surfaces that rest together when the base is coupled to the cap. With regard to recitations of "adapted to", it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claims 1, 2, 4-7, 10-12, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner, et al. (U.S. Patent 5,108,446).

Wagner, et al. disclose an implant comprising a base 1 including at least one stem 3 capable of engaging one void created in a bone structure. The stem 3 having an exterior peripherally surrounding an interior lumen. The implant also has a pin 7 that fits into the interior lumen and expands the exterior of the stem 3 (see Figure 3). The implant also has a cap 2 from which the pin 7 depends, wherein fitting the pin 7 into the interior lumen of the stem couples the cap to the base. The cap has a bearing surface and the pin 7 depends from the cap from a surface

that faces away from the bearing surface (see Figure 3). The cap and base include nesting surfaces that rest together when the base is coupled to the cap (see Figure 3). With regard the recitation that an element is "adapted to", it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Wagner, et al. also discloses the method of mounting a prosthesis in a bone structure including the steps of providing the implant; locating the implant on the bone structure 16 (see Figure 3) by placing the stem into a void formed in the bone structure 16 (see Figure 3); securing the implant by inserting the pin in the lumen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner, et al. (U.S. Patent 5,108,446).

Wagner, et al. disclose the claimed invention except for the base having a plurality of stems and also a plurality of pins. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Wagner, et al. having a plurality of stems and pins, since it has been held that mere duplication of the essential working

parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

***Allowable Subject Matter***

Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burkhead, et al.; Schryver, et al. ; Walch, et al. ; and Hunt, et al. are cited art of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

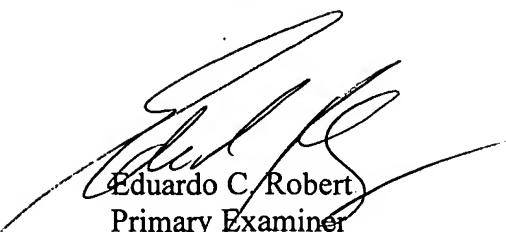
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

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Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C. Robert  
June 11, 2003